



Innovations...

Potential Catalyst for Extraordinary Medical Advances?

By Kim Parker

Could he have discovered the "fountain of youth?" David W. Moskowitz, M.D., M.A. (Oxon), FACP thinks he has. He's the Founder, Chairman and Chief Medical Officer of a St. Louis biotechnology company called GenoMed, and he thinks hydrophobic ACE inhibitors used at higher than conventional doses may be the "fountain of youth." His challenge: how do you convince the medical community when there is no money available to do large-scale clinical trials?

Moskowitz majored in chemistry (summa cum laude) at Harvard College, biochemistry (first class honours) at Merton College, Oxford, and received a medical degree (cum laude) from the Harvard-MIT Division in Health Sciences and Technology (Harvard Medical School). He trained for seven years in internal medicine and nephrology at Washington University School of Medicine before spending 11 years on the faculty of Saint Louis University School of Medicine. From 1994 to 1997, Moskowitz experienced first hand the clinical effectiveness of knowing a disease-associated gene (the angiotensin converting enzyme, or ACE, gene). Moskowitz is a pioneer in the field of medical genomics and has been recognized for his groundbreaking treatment of diseases associated with the angiotensin I-converting enzyme, such as chronic renal failure due to hypertension or Type 2 diabetes.

GenoMed is working to translate knowledge of medical genomics into clinical practice: developing better drugs, using existing drugs for new indications, and identifying diseases before symptoms arise.

GenoMed owns patents pending on a host of new disease indications for ACE inhibitors, as well as the specific dose and type of ACE inhibitor to use. Some of the diseases

Moskowitz thinks will respond include chronic kidney failure due to hypertension or Type 2 diabetes, other complications of hypertension and diabetes, many common cancers (except prostate and breast), some psychiatric diseases, and even infection with HIV and progression to AIDS.

There are many reasons to be interested in this potential discovery besides the obvious ones—Moskowitz thinks he can cut 50 percent of healthcare costs over the next decade or two if he is right and his treatments are widely adopted. Another reason is the fact that no one has ever tried to patent a treatment algorithm before.

Moskowitz explains, "The business model actually requires more creativity than the science. The science is pretty breathtaking, but at least everyone already speaks the same language. For the business model I have to invent how to deliver preventive molecular medicine. The closest analogy I can come up with is Microsoft; at the beginning, they did the unheard of thing of patenting software. Before Bill Gates, people downloaded software at no charge.

"We've always expected that biomedical research would come up with the 'fountain of youth,' so to speak. Otherwise, why would we have invested in it? Up until now, whoever discovered and developed a branded drug would just patent the drug and collect money each time the drug was used. This is the basis of the pharmaceutical industry. Fortunately or unfortunately—and from the clinical point of view, it can only be viewed as unbelievably fortunate—the 'master' disease gene turned out to be one that has been the subject of the pharmaceutical industry's activity since 1976, when captopril first appeared. ACE inhibitors have been around long enough for many to be coming off patent. Therefore, we have the novel situation of an extremely valuable drug, from the

clinical point of view, no longer having patent protection and therefore being financially valueless.

"Normally, drugs in this category would just get swept under the rug to make room for new, highly-profitable branded drugs. This may actually have been happening in the mid-90s when I first contacted the pharmaceutical industry about my findings. At about the same time, angiotensin II-receptor blockers (ARBs) began being promoted. My own data show that high-dose hydrophobic ACE inhibition is far superior to ARBs. I suppose I could just give this [finding] away for free. As an academic, I tried to. However, I have found that nobody values what he or she gets for free. Secondly, I would like to find another 3,000-5,000 disease genes, but genotyping requires lots of money. Moreover, I wouldn't mind making a living. So patenting the treatment is the only way I've been able to think of to create financial value out of this discovery," says Moskowitz.

He enrolls both the physician and the patient into GenoMed's Clinical Outcomes Improvement Program™ (COIP). The physician pays an annual fee that applies to his or her entire practice; the patient pays a similar out-of-pocket fee. The patient's fees are according to a sliding scale, ensuring that no patient will be turned away. The physician, with guidance from GenoMed, delivers the proprietary treatment approach and keeps track of the patient's outcome. In this way, GenoMed is constantly refining its notion of dosing and which particular ACE inhibitor to use. For the physician's participation in what is essentially an ongoing multi-site quality improvement plan, he or she is paid by GenoMed.

Moskowitz says, "It's a win-win situation for all concerned. The patient gets the benefit of the best treatment

already in the literature for some diseases without having to wait years more for their healthcare plan to endorse GenoMed's approach. By participating in the COIP,TM the patient and the physician help establish convincing data for an additional 160 or so diseases that look like they should benefit from effective ACE inhibition. This data should convince the 'late adapters,' which now includes most of the healthcare system. The physician is able to supplement his or her income. And GenoMed can plow its proceeds into finding new disease genes, which should improve patient outcomes even more."

To get the ball rolling, Moskowitz has created additional clinic hours to see patients who want to delay complications of diabetes and hypertension, or COPD, but who cannot find GenoMed-certified physicians to treat them. However, Moskowitz hopes to pass GenoMed's treatments on to other physicians as quickly as possible. As a further inducement, he is working with Washington University School of Medicine to offer a Web-based CME course entitled "Genomics for the Practitioner."

Moskowitz's work was recently published in three consecutive issues of *Diabetes Technology & Therapeutics* (2002), volume 4, numbers 4-6. Moskowitz is scheduled to discuss the role of medical genomics at the Art and Science of Health Promotion Conference to be held in Washington, DC in February 2003.

"The financial, political and bureaucratic incentives in the healthcare system sometimes work against patients in the guise of minimizing risk. There is clearly no point in finding all the disease genes in the world if patients cannot benefit from this knowledge. Our business model must address these obstacles squarely and courageously. If we aren't courageous, how can we expect our patients to be? Promoting health by preventing disease above all requires the courage to upset a \$2 trillion a year applecart," says Moskowitz.

For more information on GenoMed, call (314) 977-0110 or visit the Web site at www.genomedics.com.

